



1651

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Khan et. al.

Serial No.: 10/029,206

Filed: December 21, 2001

For: OLIGOPEPTIDE TREATMENT OF ANTHRAX

Confirmation No.: 5353

Examiner: To be assigned

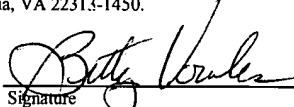
Group Art Unit: 1651

Attorney Docket No.: 2183-5222US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

March 5, 2004
Date


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Betty Vowles
Name (Type/Print)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#US- 4,977,244	12-11-1990	Muchmore et al.
#US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.
#US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.
#US- 5,958,413	09-28-1999	Anagnostopulos et al.
#US- 5,968,513	10-19-1999	Gallo et al.
#US- 5,997,871	12-07-1999	Gallo et al.
#US- 2003/0049273 A1	03-13-2003	Gallo et al.
#US- 6,583,109 B1	06-24-2003	Gallo et al.
#US- 6,596,688 B1	07-22-2003	Gallo et al.
#US- 6,620,416 B1	09-16-2003	Gallo et al.
#US- 2002/0064501	05-30-2002	Khan et al.
#US- 2002/0041871	04-11-2002	Brudnak
#US- 5,851,997	12-22-1998	Harris
#US- 6,489,296	12-03-2002	Grinnell et al.
US- 5,854,004	12-1998	Czemilofsky et al.
US- 6,361,992 B1	03-2002	Szkudlinski et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#WO 01/10907 A2	02-15-2001	University of Maryland
#WO 01/11048 A2	02-15-2001	University of Maryland
#WO 01/72831	10-04-2001	Erasmus Universiteit
#2 706 772	12-30-1994	Vacsyn
#EP 1 138 692 A1	10/04/2001	Erasmus Universiteit Rotterdam
#EP 1 300 418	04-09-2003	Erasmus Universiteit

Serial No.: 10/029,206

		Rotterdam
#WO 98/35691	08-20-1998	Proscript, Inc.
#WO 02/085117	10-31-2002	Eisai Co., Ltd.
#DE 3715662	11-19-1987	The Wellcome Foundation Ltd.
#DE 19953339	05-17-2001	Goldham Pharma GmbH
#96/04008	02-15-1996	Government of the United States
#97/49373	12-31-1997	University of Maryland Biotechnology Institute
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#CHRISTMAN et al., Nuclear factor kappaB: a pivotal role in the systemic inflammatory response syndrome and new target for therapy, Intens Care Med, 1998, pp. 1131-38, Vol. 24.

#JYONOUCHI et al., Proinflammatory and regulatory cytokine production associated with innate and adaptive immune responses in children with autism spectrum disorders and developmental regression, J Neuroim., 2001, pp. 170-79, Vol. 120.

#KANUNGO et al., Advanced Maturation of Heteropneustes Fossilis (Bloch) by Oral Administration of Human Chorionic Gonadotropin, J. Adv. Zool., 1999, pp. 1-5, Vol. 20.

#ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on Plasmodium falciparum in vitro, Zentralblatt Bakt, 1999, pp. 89-99, Vol. 289.

#TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.

#TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, *Acta Physiol Sinica*, 2003, pp. 58-64, Vol. 55.

#TOVEY et al., Mucosal Cytokine Therapy: Marked Antiviral and Antitumor Activity, *J. Interferon Cytokine Res.*, 1999, pp. 911-21, Vol. 19.

#ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 *CLINICAL & EXPERIMENTAL METASTASIS* 739 (1999).

#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 *AM. J. RESPIR. CELL MOL. BIOL.* 3-9 (1997).

#KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells *in Vitro*," 20(5-6) *PLACENTA*, page A37 (July 1999).

#KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) *HUMAN IMMUNOLOGY* 1315-1323 (December 2001).

#KHAN, Nisar A., et al., "Inhibition of Septic Shock in Mice by an Oligopeptide From the β -Chain of Human Chorionic Gonadotrophin Hormone," 63(1) *HUMAN IMMUNOLOGY* 1-7 (January 2002).

#MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, *The Journal of Immunology*, March 1997, pp. 881-86, Vol. 118, No. 3.

#MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, *Journal of Experimental Medicine*, December 1984, pp. 1672-85, Volume 160.

#PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 *ACTA NEUROCHIR (WIEN)* 76-78 (1987).

#SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin," 23(1) *TRANSPLANTATION* 103-104 (January 1977).

Serial No.: 10/029,206

#WULCZYN, F. Gregory, et al., "The NF-kB/Rel and Ikb gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996).

#YAMAMOTO, Y., et al., "Role of the NF-kB Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).

Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 10/028,075

Filed: December 21, 2001

For: GENE REGULATOR, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, Applicants offer hereby identifies the following listed copending applications naming the same inventor(s):

Attorney Docket No.: 3077-5951US
Serial No.: 10/409,027
Filing Date: 4/8/2003
Title: TREATMENT OF TRANSPLANT SURVIVAL

Attorney Docket No.: 3077-5952US
Serial No.: 10/409,032
Filing Date: 4/8/2003
Title: TREATMENT OF TRAUMA

Attorney Docket No.: 3077-5953US
Serial No.: 10/409,630
Filing Date: 4/8/2003
Title: TREATMENT OF MULTIPLE SCLEROSIS

Attorney Docket No.: 3077-5957US
Serial No.: 10/409,642
Filing Date: 4/8/2003
Title: TREATMENT OF ISCHEMIC EVENTS

Attorney Docket No.: 3077-5958US
Serial No.: 10/409,654
Filing Date: 4/8/2003
Title: TREATMENT OF NEUROLOGICAL DISORDERS

Serial No.: 10/029,206

Attorney Docket No.: 3077-5960US
Serial No.: 10/409,657
Filing Date: 4/8/2003
Title: STRATIFICATION

Attorney Docket No.: 3077-5956US
Serial No.: 10/409,659
Filing Date: 4/8/2003
Title: PEPTIDE COMPOSITIONS

Attorney Docket No.: 3077-5959US
Serial No.: 10/409,668
Filing Date: 4/8/2003
Title: ADMINISTRATION OF GENE-REGULATORY PEPTIDES

Attorney Docket No.: 3077-5955US
Serial No.: 10/409,671
Filing Date: 4/8/2003
Title: TREATMENT OF IATROGENIC DISEASE

Attorney Docket No.: 3077-5954US
Serial No.: 10/409,694
Filing Date: 4/8/2003
Title: TREATMENT OF BURNS

Attorney Docket No.: 3077-4618.1US
Serial No.: 10/678,995
Filing Date: 10/3/2003
Title: IMMUNOREGULATOR

Attorney Docket No.: 3077-6084US
Serial No.: 10/753,510
Filing Date: 1/7/2004
Title: IMMUNOREGULATORY COMPOSITIONS

Serial No.: 10/029,206

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of a first Office Action on the merits; therefore, no fee is due.

Respectfully submitted,



G. Scott Dorland, Ph.D.

Registration No. 51,622

Attorney for Applicant(s)

TRASKBRITT, P.C.

P.O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: 801-532-1922

Date: March 5, 2004

GSD/bv

Enclosures: Form PTO/SB/08

Document in ProLaw



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 4

Complete if Known

Application Number	10/029,206
Filing Date	December 21, 2001
First Named Inventor	Khan et. al.
Group Art Unit	1651
Examiner Name	To be assigned
Attorney Docket Number	2183-5222US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		#US- 4,977,244	12-11-1990	Muchmore et al.	
		#US- 5,677,275	10-14-1997	Lunardi-Iskandar et al.	
		#US- 5,877,148	03-02-1999	Lunardi-Iskandar et al.	
		#US- 5,958,413	09-28-1999	Anagnostopoulos et al.	
		#US- 5,968,513	10-19-1999	Gallo et al.	
		#US- 5,997,871	12-07-1999	Gallo et al.	
		#US- 2003/0049273 A1	03-13-2003	Gallo et al.	
		#US- 6,583,109 B1	06-24-2003	Gallo et al.	
		#US- 6,596,688 B1	07-22-2003	Gallo et al.	
		#US- 6,620,416 B1	09-16-2003	Gallo et al.	
		#US- 2002/0064501	05-30-2002	Khan et al.	
		#US- 2002/0041871	04-11-2002	Brudnak	
		#US- 5,851,997	12-22-1998	Harris	
		#US- 6,489,296	12-03-2002	Grinnell et al.	
		US- 5,854,004	12-1998	Czernilofsky et al.	
		US- 6,361,992 B1	03-2002	Szkudlinski et al.	
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		#WO 01/10907 A2	02-15-2001	University of Maryland		
		#WO 01/11048 A2	02-15-2001	University of Maryland		
		#WO 01/72831	10-04-2001	Erasmus Universiteit		
		#2 706 772	12-30-1994	Vacsyn		
		#EP 1 138 692 A1	10/04/2001	Erasmus Universiteit Rotterdam		

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SignatureDate
Considered

¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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		#EP 1 300 418	04-09-2003	Erasmus Universiteit Rotterdam		
		#WO 98/35691	08-20-1998	Proscript, Inc.		
		#WO 02/085117	10-31-2002	Eisai Co., Ltd.		
		#DE 3715662	11-19-1987	The Wellcome Foundation Ltd.		
		#DE 19953339	05-17-2001	Goldham Pharma GmbH		
		#96/04008	02-15-1996	Government of the United States		
		#97/49373	12-31-1997	University of Maryland Biotechnology Institute		
		#97/49418	12-31-1997	University of Maryland Biotechnology Institute		
		#97/49432	12-31-1997	University of Maryland Biotechnology Institute		

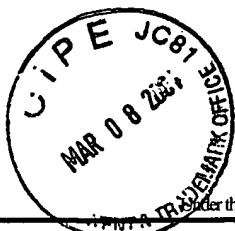
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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
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Sheet

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

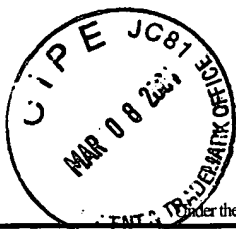
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#International Search Report, International Application No. PCT/NL02/00639, mailed August 4, 2003 (8 pages).	
		#CHRISTMAN et al., Nuclear factor kappaB: a pivotal role in the systemic inflammatory response syndrome and new target for therapy, Intens Care Med, 1998, pp. 1131-38, Vol. 24.	
		#JYONOUCHI et al., Proinflammatory and regulatory cytokine production associated with innate and adaptive immune responses in children with autism spectrum disorders and developmental regression, J Neuroim., 2001, pp. 170-79, Vol. 120.	
		#KANUNGO et al., Advanced Maturation of Heteropneustes Fossilis (Bloch) by Oral Administration of Human Chorionic Gonadotropin, J. Adv. Zool., 1999, pp. 1-5, Vol. 20.	
		#ROHRIG et al., Growth-stimulating Influence of Human Chorionic Gonadotropin (hCG) on Plasmodium falciparum in vitro, Zentralblatt Bakt, 1999, pp. 89-99, Vol. 289.	
		#TAK et al., NF-kappaB: a key role in inflammatory diseases, J Clin Invest., 2001, pp. 7-11, Vol. 107.	
		#TAN et al., The role of activation of nuclear factor-kappa B of rat brain in the pathogenesis of experimental allergic encephalomyelitis, Acta Physiol Sinica, 2003, pp. 58-64, Vol. 55.	
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Group Art Unit	1651
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Attorney Docket Number	2183-5222US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#ALBINI, A., et al., "Old drugs as novel angiogenesis inhibitors: Preclinical studies with NAC, hCG, EGCG and somatostatin," 17 CLINICAL & EXPERIMENTAL METASTASIS 739 (1999).	
		#BLACKWELL, Timothy S., et al., "The Role of Nuclear Factor-kB in Cytokine Gene Regulation," 17 AM. J. RESPIR. CELL MOL. BIOL. 3-9 (1997).	
		#KELLER, S., et al., "Human Chorionic Gonadotropin (hCG) Is a Potent Angiogenic Factor for Uterine Endothelial Cells <i>in Vitro</i> ," 20(5-6) PLACENTA, page A37 (July 1999).	
		#KHAN, Nisar A., et al., "Inhibition of Diabetes in NOD Mice by Human Pregnancy Factor," 62(12) HUMAN IMMUNOLOGY 1315-1323 (December 2001).	
		#KHAN, Nisar A., et al., "Inhibition of Septic Shock in Mice by an Oligopeptide From the β -Chain of Human Chorionic Gonadotrophin Hormone," 63(1) HUMAN IMMUNOLOGY 1-7 (January 2002).	
		#MUCHMORE et al., Immunoregulatory Properties of Fractions from Human Pregnancy Urine: Evidence that Human Chorionic Gonadotropin is not Responsible, The Journal of Immunology, March 1997, pp. 881-86, Vol. 118, No. 3.	
		#MUCHMORE et al., Purification and Characterization of a Mannose-Containing Disaccharide Obtained from Human Pregnancy Urine, Journal of Experimental Medicine, December 1984, pp. 1672-85, Volume 160.	
		#PATIL, A., et al., "The Study of the Effect of Human Chorionic Gonadotrophic (HCG) Hormone on the Survival of Adrenal Medulla Transplant in Brain. Preliminary Study," 87 ACTA NEUROCHIR (WIEN) 76-78 (1987).	
		#SLATER, Lewis M., et al., "Decreased Mortality of Murine Graft-Versus-Host Disease by Human Chorionic gonadotropin," 23(1) TRANSPLANTATION 103-104 (January 1977).	
		#WULCZYN, F. Gregory, et al., "The NF-kB/Rel and I κ B gene families: mediators of immune response and inflammation," 74(12) J. MOL. MED. 749-769 (1996).	
		#YAMAMOTO, Y., et al., "Role of the NF-kB Pathway in the Pathogenesis of Human Disease States," 1(3) CURRENT MOLECULAR MEDICINE 287-296 (July 2001).	

Examiner
SignatureDate
ConsideredPursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/821,380

Filed: March 29, 2001

For: IMMUNOREGULATOR, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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